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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

POUS, NATALIE R

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/505,272

Applicant(s)

KERR, STEPHEN

Examiner

Natalie Pous

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/22/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "said trigger" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Regarding Claim 1, Gordon teaches a device for fashioning a closure of a puncture site in a tissue (2) comprising: a cannula member (32) having proximal and distal ends and a lumen; a connecting rod (38) disposed axially within said cannula, said connecting rod having a proximal end oriented towards said proximal end of said

Art Unit: 3731

cannula and a distal end oriented toward said distal end of said cannula, said connecting rod having an actuating mechanism (124) operative to selectively cause said connecting rod to advance distally or retract proximally within said cannula (fig. 2 to fig. 3) a needle/suture complex (42) mounted upon said distal end of said connecting rod (38), said needle/suture complex comprising at least one pair of needles (6) having a suture extending therebetween (4), said needles being operative to assume an operative configuration wherein said needles extend in opposed directions from the distal end of said cannula such that each respective needle extends from a periphery of a puncture site (fig. 1b); and a needle trap mechanism (16) disposed within the lumen of said cannula and operative to lockingly engage said needles (6) of said needle/suture complex when said needles assume the operative configuration; and wherein said needle trap mechanism is operative to draw said needles into the lumen of said cannula (fig. 1g) such that the device may be withdrawn from the puncture site with the suture extending between the needles, forming a closure of said puncture site (fig. 1h).

Regarding Claim 2, Gordon teaches the device of claim 1, wherein said needles (6) are further operative to assume one or both of the following additional configurations: a folded configuration wherein said needles are operative to extend through the lumen of said cannula, and a retracted wherein said needles are biased inwardly toward the lumen of said cannula (fig. 1d).

Regarding Claim 3, Gordon teaches the device of claim 2 wherein the distal end of said cannula (32) is positionable through a puncture site in a tissue (14).

Regarding claim 4, Gordon teaches the device of claim 2 wherein said needle/suture complex further comprises at least one pair of needle holder arms (10), each respective one of said at least one pair of said needle holder arms being operative to receive a respective one of said pair of needles (6).

Regarding Claim 5, Gordon teaches the device of claim 4 wherein each respective one of said pair of needles is operative to disengage from said needle holder arms as said needle/suture complex transitions from its second operative configuration to its third operative configuration (fig. 1d to fig. 1e).

Regarding Claim 6, Gordon teaches the device of claim 2 wherein each respective one of said pair of needles are biased to extend in diametrically opposed directions across said puncture site as said needle/suture complex assumes said second operative configuration (fig. 1b).

Regarding Claim 7, Gordon teaches the device of claim 4 wherein each respective one of said pair of needle holder arms are biased to extend in diametrically opposed directions across said puncture site as said needle holder arms assume said second operative configuration (fig. 1b).

Regarding Claim 8, Gordon teaches the device of claim 1 further comprising a handle (34a) formed upon said cannula.

Regarding Claim 9, Gordon teaches the device of claim 8 wherein said handle (34a) and said trigger (124) are positioned relative one another to enable the handle to be grasped and the trigger to be manipulated by a single hand of a user.

Regarding Claim 14, Gordon teaches the device of claim 1 wherein said actuating mechanism is a trigger (124).

4. Claims 1, 2 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Klein et al. (US 5860991).

Regarding Claim 1, Klein teaches a device for fashioning a closure of a puncture site in a tissue (10) comprising: a cannula member (s) having proximal and distal ends and a lumen; a connecting rod (14) disposed axially within said cannula, said connecting rod having a proximal end oriented towards said proximal end of said cannula and a distal end oriented toward said distal end of said cannula, said connecting rod having an actuating mechanism (16) operative to selectively cause said connecting rod to advance distally or retract proximally within said cannula (fig. 10 to fig. 11) a needle/suture complex (18) mounted upon said distal end of said connecting rod, said needle/suture complex comprising at least one pair of needles (20) having a suture extending therebetween (30), said needles being operative to assume an operative configuration wherein said needles extend in opposed directions from the distal end of said cannula such that each respective needle extends from a periphery of a puncture site (BV); and a needle trap mechanism (32) disposed within the lumen of said cannula and operative to lockingly engage said needles (20) of said needle/suture complex when said needles assume the operative configuration; and wherein said needle trap mechanism is operative to draw said needles into the lumen of said cannula (fig. 11)

such that the device may be withdrawn from the puncture site with the suture extending between the needles, forming a closure of said puncture site (fig. 12).

Regarding Claim 2, Klein teaches the device of claim 1, wherein said needles (20) are further operative to assume one or both of the following additional configurations: a folded configuration wherein said needles are operative to extend through the lumen of said cannula, and a retracted wherein said needles are biased inwardly toward the lumen of said cannula (fig. 11).

Regarding Claim 10, Klein teaches the device of claim 2 wherein said needle trap mechanism comprises a cylindrical sleeve (32) axially mounted about said connecting rod (14) within said cannula (s), said needle trap mechanism having a proximal end with a lever (16) formed thereon, extending from said cannula, and a bell shaped distal end (fig. 9) having a needle catch (32) formed therein, said needle catch being operative to lockingly engage with said needle tips of said needle/suture complex when said complex assumes said third operative configuration.

Regarding Claim 11, Klein teaches the device of Claim 10 wherein said lever formed upon said needle trap mechanism is operative to cause said needle trap mechanism to extend distally and retract proximally within the said cannula (fig. 10 to fig. 11).

Regarding Claim 12, Klein teaches the device of claim 11 wherein said needle trap mechanism, when lockingly engaged with said needle tips of said needles, captures said needles within said cannula when said needle trap mechanism retracts proximally within said cannula (fig. 10 to fig. 11).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon as a matter of design choice. Gordon teaches all aspects of preceding dependent claim 1, but fails to disclose wherein a tapered mount is formed upon said distal end of said connecting rod and holding said needle/suture complex, said tapered mount having a generally hourglass shape. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distal end of the connecting rod of Gordon with an hourglass shaped tapered mount since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. In re *Karlson*, 136 USPQ 184.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29

Art Unit: 3731

USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 and 3-12 of U.S. Patent No. 6743241.

Although the conflicting claims are not identical, they are not patentably distinct from each other because patent # 6743241 claims all limitations of the application including: a cannula member, a connecting rod, an actuating mechanism to cause the connecting rod to advance distally or retract proximally within the cannula, a needle/suture complex mounted on the end of the connecting rod, at least a pair of needles having a suture therebetween, a needle trap mechanism to lockingly engage the needles and operative to draw the needles into the lumen of the cannula, and all limitations of the dependent claims.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP
1/17/06



(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER